

**STATE OF MISSOURI
MISSOURI BOARD OF PHARMACY**

HOWARD STARK PROFESSIONAL)	
PHARMACY, INC.)	
d/b/a STARK PHARMACY)	Complaint No. 2016-003134
5701 W 119 th Street)	
Overland Park, KS 66209)	
Permit No. 2011033273)	

**SETTLEMENT AGREEMENT BETWEEN
MISSOURI BOARD OF PHARMACY AND HOWARD STARK
PROFESSIONAL PHARMACY, INC. d/b/a STARK PHARMACY**

Come Now Howard Stark Professional Pharmacy Inc. d/b/a Stark Pharmacy ("Respondent" or "Stark Pharmacy") and the Missouri Board of Pharmacy ("Board" or "Petitioner") and enter into this Settlement Agreement ("Settlement Agreement") for the purpose of resolving the question of whether Respondent's permit to operate a pharmacy will be subject to discipline. For purposes of the terms included herein, including the disciplinary period, as defined below, the effective date of this Settlement Agreement is July 5, 2019 (the "Effective Date").

Pursuant to the terms of Section 536.060, RSMo, the parties hereto waive the right to a hearing by the Administrative Hearing Commission of the State of Missouri ("Administrative Hearing Commission") and, additionally, the right to a disciplinary hearing before the Board under Section 621.110, RSMo, and stipulate and agree that a final disposition of this matter may be effectuated as described below.

Respondent acknowledges that it understands the various rights and privileges afforded it by law, including the right to a hearing of the charges against it; the right to appear and be represented by counsel; the right to have all charges against it proved upon the record by competent and substantial evidence; the right to cross-examine any witnesses appearing at the hearing against it; the right to a decision upon the record by a fair and impartial administrative hearing

commissioner concerning the charges pending against it and, subsequently, the right to a disciplinary hearing before the Board at which time it may present evidence in mitigation of discipline; and the right to recover attorney's fees incurred in defending this action against its permit. Being aware of these rights provided it by operation of law, Respondent knowingly and voluntarily waives each and every one of these rights and freely enters into this Settlement Agreement and agrees to abide by the terms of this document, as they pertain to it.

Respondent acknowledges that it has received a copy of the complaint (the "Complaint") filed with the Administrative Hearing Commission, the investigative report, and other documents relied upon by the Board in determining there was cause for discipline against Respondent's permit.

For the purpose of settling this dispute, Respondent stipulates that the factual allegations contained in this Settlement Agreement are true and stipulates with the Board that Respondent's permit to operate a pharmacy, numbered 2011033273, is subject to disciplinary action by the Board in accordance with the provisions of Chapter 621 and Chapter 338, RSMo.

JOINT STIPULATION OF FACTS

1. The Missouri Board of Pharmacy is an agency of the State of Missouri created and established pursuant to §338.110, RSMo¹, for the purpose of executing and enforcing the provisions of Chapter 338, RSMo.

2. Howard Stark Professional Pharmacy, Inc. d/b/a Stark Pharmacy ("Respondent" or "Stark Pharmacy"), 5701 W 119th Street, Overland Park, Kansas, is permitted by the Board under permit number 2011033273. Respondent's permit was at all times relevant herein current and active.

¹ All statutory references are to the 2000 Revised Statutes of Missouri, as amended, unless otherwise stated.

3. Howard Stark Professional Pharmacy, Inc. d/b/a Howard Stark Professional Pharmacy was located at 6675 Holmes, Kansas City, MO 64131 ("Howard Stark Pharmacy").

4. At all relevant times herein, the owners of Howard Stark Pharmacy and Respondent were Steven John Schafer, Steven D. Baraban and Gary Gray, each with a one-third ownership interest in both pharmacies.

5. At all relevant times herein, Steven John Schafer ("Schafer") was the Pharmacist-in-Charge ("PIC") of Respondent.

6. At all relevant times herein, Steven D. Baraban ("Baraban") was the PIC of Howard Stark Pharmacy.

7. From 2013 until December, 2015, Howard Stark Pharmacy ordered and purchased drug ingredients used in pain cream compound preparations it dispensed to Missouri patients.

8. The drug ingredients used in the pain creams were shipped directly to Howard Stark Pharmacy from the suppliers.

9. Howard Stark Pharmacy shipped or delivered the drug ingredients used in the pain creams to Stark Pharmacy.

10. The drug ingredients Howard Stark Pharmacy ordered, purchased, transferred and distributed to Stark Pharmacy included tramadol, ketamine, ketoprofen, baclofen, diclofenac, cyclobenzaprine, versapro cream, lidocaine hcl, lidocaine base, gabapentin, nifedipine, flurbiprofen, prilocaine, bupivacaine, imipramine, lamotrigine 100mg, meloxicam 15mg, and lidocaine/prilocaine cream 2.5/2.5%.

11. Stark Pharmacy used the drug ingredients it received from Howard Stark Pharmacy to make batch compound pain creams, which were ultimately dispensed to patients by Howard Stark Pharmacy.

12. Pursuant to the practice of anticipatory compounding, Baraban contacted Stark Pharmacy by telephone and told Stark Pharmacy which medications Howard Stark Pharmacy needed to be compounded.

13. A dedicated staff member of Stark Pharmacy personally drove batches of compounded pain cream preparations to Howard Stark Pharmacy.

14. These compounded pain creams were driven from Stark Pharmacy to Howard Stark Pharmacy in 60 or 120-gram bottles. Each individual compound was labeled with the formula ID number and lot number of the medication.

15. Howard Stark Pharmacy then added a patient-specific label generated from its computer system to the bottles when it dispensed the prescriptions to its patients.

16. Stark Pharmacy created batch compound log records for the batch compounds it prepared for Howard Stark Pharmacy.

17. Neither Howard Stark Pharmacy nor Stark Pharmacy had a Missouri Class J pharmacy permit.

18. Stark Pharmacy did not record prescription numbers on its batch compound log records for compounds dispensed by Howard Stark Pharmacy.

19. Howard Stark Pharmacy created a patient-specific compound log for each prescription dispensed from Howard Stark Pharmacy from a batch compound prepared at and by Stark Pharmacy and delivered to Howard Stark Pharmacy.

Failure to obtain and comply with Class J permit requirements

20. A Class J Shared Service pharmacy permit is defined in 20 CSR § 2220-2.020(9) as follows:

(J) Class J: Shared Service. A pharmacy engaged in the processing of a request from another pharmacy to fill or refill a prescription drug order, or

that performs or assists in the performance of functions associated with the dispensing process, drug utilization review (DUR), claims adjudication, refill authorizations, and therapeutic interventions;

21. Missouri law defines the circumstances under which a pharmacy may share services with another pharmacy, which includes each pharmacy location obtaining a Class J permit, to-wit:

(1) Class J: Shared Services: Shared Service Pharmacy is defined as the processing by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order, or that performs or assists in the performance of functions associated with the dispensing process, drug utilization review (DUR), claims adjudication, refill authorizations, and therapeutic interventions.

(A) A pharmacy may perform or outsource centralized prescription processing services provided the parties:

1. Have the same owner, or have a written contract outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of said contract in compliance with federal and state laws and regulations;
2. Maintain separate licenses for each location involved in providing shared services; and
3. Share a common electronic file to allow access to sufficient information necessary or required to fill or refill a prescription drug order.

(B) There must be record keeping systems between shared service pharmacies with real time on-line access to shared services by both pharmacies. . . .

(C) The parties performing or contracting for centralized prescription processing services shall maintain a policy and procedures manual and documentation that implementation is occurring in a manner that shall be made available to the board for review upon request and that includes, but is not limited to, the following:

1. A description of how the parties will comply with federal and state laws and regulations;
2. The maintenance of appropriate records to identify the responsible pharmacist(s) in the dispensing and counseling processes;

3. The maintenance of a mechanism for tracking the prescription drug order during each step in the process;
4. The provision of adequate security to protect the confidentiality and integrity of patient information;
5. The maintenance of a quality assurance program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care and resolve identified problems.

20 CSR § 2220-2.650(1).

22. Stark Pharmacy violated 20 CSR § 2220-2.650(1)(A) by failing to maintain a Class J permit and by sharing services with Howard Stark Pharmacy which also did not have a Class J permit.

23. Stark Pharmacy violated 20 CSR § 2220-2.650(1)(C) by failing to maintain a policy and procedures manual relating to its shared prescription processing services.

24. By operating as a Class J pharmacy without a valid Class J pharmacy permit, Stark Pharmacy also violated § 338.220.1(10), RSMo, which prohibits the opening, establishment, operation, or maintenance of a pharmacy without first obtaining a proper permit from the Board, to-wit:

1. It shall be unlawful for any person, copartnership, association, corporation or any other business entity to open, establish, operate, or maintain any pharmacy as defined by statute without first obtaining a permit or license to do so from the Missouri board of pharmacy. The following classes of pharmacy permits or licenses are hereby established:

* * *

(10) Class J: Shared service.

CONCLUSIONS OF LAW

25. Cause exists for Petitioner to take disciplinary action against Respondent's pharmacy permit under §338.055.2,(6), (12), and (15), RSMo, which states, in pertinent parts:

2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:

* * *

(6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;

* * *

(12) Failure to display a valid certificate or license if so required by this chapter or any rule promulgated hereunder;

* * *

(15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government.

JOINT AGREED DISCIPLINARY ORDER

Based upon the foregoing, the parties mutually agree and stipulate that the following shall constitute the disciplinary order entered by the Board in this matter under the authority of Section 621.045.1, RSMo:

A. Respondent's permit numbered 2011033273 shall be placed on **PROBATION** for a period of **THREE (3) YEARS** ("disciplinary period"). The period of probation shall constitute the disciplinary period. The terms of discipline shall be as follows:

The following terms apply for the entire disciplinary period.

1. Respondent shall pay all required fees for licensing to the Board and shall renew its pharmacy license prior to October 31 of each licensing year.
2. Respondent shall comply with all provisions of Chapter 338, Chapter 195, and all applicable federal and state drug laws, rules and regulations and with all federal

and state criminal laws. "State" here includes the State of Missouri and all other states and territories of the United States.

3. If requested, Respondent shall provide the Board a list of all licensed pharmacists employed by the Respondent, and the individuals' current home addresses and telephone numbers.
4. If, after disciplinary sanctions have been imposed, Respondent fails to keep its pharmacy license current, the period of unlicensed status shall not be deemed or taken as any part of the time of discipline so imposed.
5. Respondent shall report to the Board, on a preprinted form supplied by the Board office, once every six (6) months (due by each January 1 and July 1), beginning with whichever date occurs first after this Agreement becomes effective, stating truthfully whether or not it has complied with all terms and conditions of its disciplinary order.
6. Respondent shall not serve as an intern training facility for Missouri interns.
7. Respondent shall make a representative of the pharmacy available for personal interviews to be conducted by a member of the Board or the Board of Pharmacy staff. Said meetings will be at the Board's discretion and may occur periodically during the disciplinary period. Respondent will be notified and given sufficient time to arrange these meetings.
8. Respondent's failure to comply with any condition of discipline set forth herein constitutes a violation of this disciplinary Agreement.
9. The parties to this Agreement understand that the Board of Pharmacy will maintain this Agreement as an open record of the Board as provided in Chapters 324, 338, 610, RSMo.

B. Upon the expiration of said disciplinary period, Respondent's license as a pharmacy in Missouri shall be fully restored if all other requirements of law have been satisfied provided, however, that in the event the Board determines that the Respondent has violated any term or condition of this Settlement Agreement, the Board may, in its discretion, after an evidentiary hearing, vacate and set aside the discipline imposed herein and may suspend, revoke, or otherwise lawfully discipline Respondent.

C. No order shall be entered by the Board pursuant to the preceding paragraph of this Settlement Agreement without notice and an opportunity for Respondent to be heard before the Board, or Administrative Hearing Commission if such a hearing is required by law, in accordance with the provisions of Chapter 536, RSMo.

D. If the Board determines that Respondent has violated a term or condition of this Settlement Agreement, which violation would also be actionable in a proceeding before the Administrative Hearing Commission or the circuit court, the Board may elect to pursue any lawful remedies or procedures afforded it and is not bound by this Settlement Agreement in its determination of appropriate legal actions concerning that violation. If any alleged violation of this Settlement Agreement occurred during the disciplinary period, the Board may choose to conduct a hearing before it either during the disciplinary period, or as soon thereafter as a hearing can be held to determine whether a violation occurred and, if so, it may impose further discipline. The Board retains jurisdiction to hold a hearing to determine if a violation of this Settlement Agreement has occurred.

E. The terms of this Settlement Agreement are contractual, legally enforceable, binding, and not merely recitals. Except as otherwise contained herein, neither this Settlement Agreement nor any of its provisions may be changed, waived, discharged, or terminated, except by an instrument in writing signed by the party against whom the enforcement of the change, waiver, discharge, or termination is sought.

F. Respondent hereby waives and releases the Board, its members and any of its employees, agents, or attorneys, including any former board members, employees, agents, and attorneys, of, or from, any liability, claim, actions, causes of action, fees, costs, and expenses, and compensation, including, but not limited to, any claims for attorney's fees and expenses, including

any claims pursuant to Section 536.087, RSMo, or any claim arising under 42 U.S.C. §1983, which may be based upon, arise out of, or relate to any of the matters raised in this litigation, or from the negotiation or execution of this Settlement Agreement. The parties acknowledge that this paragraph is severable from the remaining portions of this Settlement Agreement in that it survives in perpetuity even in the event that any court of law deems this Settlement Agreement or any portion thereof void or unenforceable.

RESPONDENT, AS EVIDENCED BY THE INITIALS ON THE APPROPRIATE LINE,

_____REQUESTS

___X___DOES NOT REQUEST

THE ADMINISTRATIVE HEARING COMMISSION TO DETERMINE IF THE FACTS SET FORTH HEREIN ARE GROUNDS FOR DISCIPLINING RESPONDENT'S LICENSE AS A PHARMACY.

If Respondent has requested review, Respondent and Board jointly request that the Administrative Hearing Commission determine whether the facts set forth herein are grounds for disciplining Respondent's permit and issue findings of fact and conclusions of law stating that the facts agreed to by the parties are grounds for disciplining Respondent's permit. Effective fifteen (15) days from the date the Administrative Hearing Commission determines that the Settlement Agreement sets forth cause for disciplining Respondent's permit, the agreed upon discipline set forth herein shall go into effect.

If Respondent has not requested review by the Administrative Hearing Commission, the Settlement Agreement goes into effect fifteen (15) days after the document is signed by the Board's Executive Director.

RESPONDENT

HOWARD STARK
PROFESSIONAL PHARMACY,
INC. d/b/a STARK PHARMACY

By: 

As Authorized Agent for
HOWARD STARK
PROFESSIONAL
PHARMACY, INC.
d/b/a STARK PHARMACY

Printed: Stephen J Schafner

Date: 6-6-19

PETITIONER

MISSOURI BOARD OF
PHARMACY

By: 

Kimberly Grinston
Executive Director

Date: 6-20-19

NEWMAN, COMLEY & RUTH P.C.

By: 

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